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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,391	11/14/2000	Jurgen Bongs	02481.1716	3417

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,391

Applicant(s)

Bongs et al.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 16, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above, claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The application should be reviewed for errors. Error occurs, for example, in the spelling of "methacryamide" in claim 22 and in the recitation "one more enzyme" in claim 12.. The amendment filed 10/16/02 is acknowledged. Claims 12-23 are being considered on the merits. Claim 11 is withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is confusing in that it lacks internal antecedent basis for "said biomolecules". Which "biomolecules" are obtained? There is no clear indication as to their source or nature. the preamble is directed to "a process of extraction".

Claim 13 remains vague, indefinite and confusing in the recitation of "insulins and their analogs". It is unclear what is intended to be encompassed by "analogs" in this context. Is it analogy by structure or by function? In addition, nature of "corresponding precursors" of these analogs is not set forth.

The information presented at page 3 of the specification does not clarify the nature extent of the analogs encompassed by the invention, but merely indicates how some analogs may be obtained.

Claims 12 and 13 are vague, indefinite and confusing in the recitation of "substantially no pores". The number of pores intended is not disclosed in the as-filed specification. Therefore, the number of pores intended to be claim designated cannot be discerned with any precision.

Applicants citation of page 3, lines 19-21 as providing a definition for "substantially no pores" is puzzling. The terms "substantially no pores" are not found at the cited location. The cited portion reads in part "the polymeric support material has no or almost no pores which are large enough that the enzymes can bind to the support within these pores". The extent of "almost no pores" is not indicated. Is it 0.00001%, 0.001%, 1%, 10%, 15%, 25% or more pores?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Lorenzen *et al.*

The claims are directed to the enzymatic extraction of biomolecules such as peptides using a polymeric support material which has no pores or substantially no pores.

The reference teaches the enzymatic extraction of the biomolecules phosphopeptides from casein using a polymeric support material which has no pores or substantially no pores, such as oxirane acrylic beads using trypsin (See, e.g., page 119, Materials and Methods.)

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants assert that the benefits of the claimed invention were not obtained with Eupergit C. However, no evidence has been provided on this the record to substantiate that this material does not meet the property of having "substantially no pores".

Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakubke *et al.* taken with Lorenzen *et al.*, Eckstein, Huwig *et al.* and Hillegas *et al.* for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to the enzymatic extraction of insulin using a polymeric support material which has no pores or substantially no pores.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants arguments are directed generally to the performance of enzymatic chemical reactions. However, the invention as claimed is directed to "extraction" processes wherein the substrate is not clearly delineated.

In response to applicant's arguments that the support used by Lorenzen is not "pore free" it is noted that the claimed invention includes a support which has "substantially no pores", terminology which is not defined in the as filed specification. Therefore, these arguments are not relevant to the invention as claimed. In addition, the instant record does not clearly set forth the extent of pores present in Eupergit C or the effect of using this material for any and all biomolecules. The extent of pores on other carriers, such as Eupergit^R C250L is also unclear, particularly with respect to "substantially no pores".

Even though Hillegas does not specifically attach enzymes to the support, it is noted that the cells which are attached would reasonably be expected to comprise enzymes, which are required to retain activity for their metabolic process and consequent survival. Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in using the support of Hillegas to immobilize enzymes *per se* rather than enzymes contained in cells. Therefore, this reference is properly combinable with references directed to the immobilization of enzymes for enzymatic process.

It is of interest to note that the present record only shows comparative examples wherein improved results are demonstrated with respect to the effect of trypsin immobilized on the specific support Eupergit^R C1Z and having a particular activity on the production of insulin from preproinsulin at specific process conditions. However, this is not the invention as claimed. For example, claim 12 is directed broadly to the production of peptides, proteins, oligosaccharides and polysaccharides with unidentified enzymes and claim 13 is directed to extracting insulins and

producing "biomolecules" with unidentified enzymes. Therefore, the results touted have no clear correlation with the claim designated invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651